DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 24, 2015

TherOzone USA, Inc.
Ms. Rebecca K Pine
Official Correspondent
2701 Ocean Park Blvd, Suite 108
Santa Monica, CA 90405

Re: K141504
Trade/Device Name: T-8000 TherOzone Unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit (accessory)
Regulatory Class: II
Product Code: EIA
Dated: January 27, 2015
Received: January 28, 2015

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141504

Device Name
T-8000 TherOzone Unit

Indications for Use *(Describe)*
The T-8000 TherOzone Unit is intended for the reduction of microorganisms in dental unit water lines.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

6. 510(k) Summary

This 510(k) [K141504] summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	TherOzone USA, Inc.
DATE PREPARED:	February 24, 2015
CONTACT PERSON:	Rebecca K Pine Official Correspondent TherOzone USA, Inc. 2701 Ocean Park Blvd, Suite 108 Santa Monica, CA 90405 Phone: 760.809.5178 FAX: 760.290.3216 Email: beky@cox.net
TRADE NAME:	T-8000 TherOzone Unit
COMMON NAME:	Accessory, Dental Unit
CLASSIFICATION NAME:	Dental Operative Unit (accessory)
DEVICE CLASSIFICATION:	Class II, per 21 CFR 872.6640
PRODUCT CODE	EIA
PREDICATE DEVICES:	UltraKleen(K991946) Odyssey Dental Water Unit (K964796)

Substantially Equivalent To:
The T-8000 TherOzone Unit is substantially equivalent in intended use, principal of operation and technological characteristics to the existing UltraKleen and the Odyssey Dental Water Unit devices.

Description of the Device Subject to Premarket Notification:
The T-8000 TherOzone Unit is a device intended to clean dental unit water lines. The device consists of an ozone generator and dispensing bottles.

Indication for Use:
The T-8000 TherOzone Unit is intended for the reduction of microorganisms in dental unit water lines.

Technical Characteristics:
The T-8000 TherOzone Unit has similar physical and technical characteristics to the predicate devices, as illustrated in the table below.

	T-8000 TherOzone Unit	Odyssey I Dental Water Unit Germiphene Corp. (K964796)	UltraKleen, Sterilex (K991946)	Substantial Equivalence
Indications for Use	For the reduction of microorganisms in dental unit water lines.	Indicated to be used as an in-line water disinfecting system to reduce microorganisms in the dental water lines	The product has been specially formulated and clinically proven to clean deposits and control bacterial contamination in Dental Unit Water Lines.	Although minor grammatical difference exist, the intended use of the subject device is substantially equivalent to the predicate devices
Function	Dental unit water line cleaner	Dental unit water line cleaner	Dental unit water line cleaner	Same. The subject device is substantially equivalent to the predicate devices.
Principle of Operation	Creates ozone from air. Ozonated gas (in water) applied to dental unit water lines	Creates ozone from air. Ozonated gas (in water) applied to dental unit water lines	Anti-microbial chemical agent	Same. The subject device is substantially equivalent to the predicate device.
Mechanism of Action	Oxidation, leading to cell lysis	Oxidation, leading to cell lysis	Oxidation Hydrolysis Microbubbling	Same. The subject device is substantially equivalent to the predicate device.
Patient contact	None	In-line use	None	Same. The subject device is substantially equivalent to the predicate device.
Intended User	Dental professional	Dental professional	Dental professional	Same. The subject device is substantially equivalent to the predicate devices.
Delivery to Site	Direct application to dental water lines	Direct application to dental water lines	Direct application to dental water lines	Same. The subject device is substantially equivalent to the predicate devices.
Microorganism reduction cycle	Daily flush through water lines	Continuous flush	Flush with overnight soak	Similar. The subject device cycle varies slightly, but all device cycles are designed for

	T-8000 TherOzone Unit	Odyssey I Dental Water Unit Germiphene Corp. (K964796)	UltraKleen, Sterilex (K991946)	Substantial Equivalence
				effective microorganism reduction. The minor differences do not pose a functional difference, therefore the subject device is substantially equivalent to the predicate devices.
Materials (wetted)	Polyethylene Fluoropolymers	Polycarbonate, 304V stainless steel, Kynar, polyethylene	Sodium carbonate Sodium percarbonate Benzenemethanaminium, N, N-dimethyl-N-tetradecyl-. Chloride Tetrasodium EDTA	Similar, subject device and the predicate device are both fabricated from common medical device materials, therefore the subject device and predicate device are substantially equivalent
Air Supply	Ambient, compressed to 5-25psi	60 PSIG, min	N/A	Same. The subject device and predicate device both use a pressurized air source. The differences in operating parameters are minor and do not affect the fundamental technology therefore the subject device and the predicate device are substantially equivalent.
Electrical	100-240VAC,50-60Hz,1.5 65 watts	100-130 VAC, 50-60 Hz, 20 watts, grounded	N/A	Same. The subject device and predicate device both use electrical power. The differences in electrical specifications are

	T-8000 TherOzone Unit	Odyssey I Dental Water Unit Germiphene Corp. (K964796)	UltraKleen, Sterilex (K991946)	Substantial Equivalence
				minor and do not affect the fundamental technology therefore the subject device and the predicate device are substantially equivalent.
Water capacity	~ 600mL	1 liter (1,000 mL)	N/A	Same. The minor differences in volume do not affect the fundamental technology therefore the subject device and the predicate device are substantially equivalent.
Water requirements	Distilled only	Distilled only	Distilled only	Same. The subject device is substantially equivalent to the predicate device.
Equipment Weight (dry)	12 lbs	7 lbs	N/A	Same. The minor differences in equipment weight do not affect the fundamental technology therefore the subject device and the predicate device are substantially equivalent.
Dimensions	8"x 9.5" X 18 ¼"	6" x 6" x 12 ½ "	N/A	Same. The minor differences in equipment dimension do not affect the fundamental technology therefore the subject device and the predicate device are substantially equivalent.
How provided	Non-sterile, reusable	Non-sterile, reusable	Non-sterile, single use	Same. The subject device is

	T-8000 TherOzone Unit	Odyssey I Dental Water Unit Germiphene Corp. (K964796)	UltraKleen, Sterilex (K991946)	Substantial Equivalence
				substantially equivalent to the predicate device.

Performance Data:
All necessary verification and validation testing has been performed for the T-8000 TherOzone Unit to assure substantial equivalence to the predicate devices and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Performance Testing included:

- Microbial challenge
- Software Validation
- Environmental Evaluation
- Functional Verification
- Material Compatibility Analysis
- Usability Evaluation
- Pressure Verification
- Environmental Condition Verification

The performance testing conducted demonstrates that the T-8000 TherOzone Unit is substantially equivalent to the predicate devices.

Basis for Determination of Substantial Equivalence:
Based on the intended use, indications for use, technological characteristics, performance data and nonclinical tests performed, the subject T-8000 TherOzone Unit is substantially equivalent and is as safe and as effective as the legally marketed predicate devices, UltraKleen(K991946) and Odyssey Dental Water Unit (K964796).